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EXAMINER

FERNANDEZ RIVAS, OMAR F

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/520,409	<b>Applicant(s)</b> KATES ET AL.	
	<b>Examiner</b> OMAR F. FERNANDEZ RIVAS	<b>Art Unit</b> 2129	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This Office Action is in response to an AMENDMENT entered on 6/23/2009.
2. The Office Action of 12/23/2008 is incorporated into this Final Office Action by reference.

### **Status of Claims**

3. Claims 2-20 have been amended. Claim 1 has been cancelled. Claims 2-20 are pending on this application.

### ***Specification***

4. The arguments regarding the objection of the abstract have been considered and are persuasive. The requirement of 37 CFR 1.52(b) that the abstract "commence on a separate physical sheet or electronic page" does not apply to the copy of the published international application communicated to the designated Offices by the International Bureau under PCT Article 20. Accordingly, the U.S. national stage application does not require an abstract commencing on a separate sheet if the abstract does not appear on a separate sheet in the publication of the international application. The objection made on the specification in the previous Office Action is withdrawn.

### ***Claim Objections***

5. In light of the amendments made, the objection made in the previous Office Action is withdrawn.

Art Unit: 2129

6. Claims 6, 11, 12 and 13 are objected to because of the following informalities:

#### **Claim 6**

The claim recites “A method of training at least two learning-capable systems according to the method of claim 5, wherein the training step comprises the steps of: ...” This claim should be amended to make it clear that this is a dependent claim further limiting the method of claim 5, which depends on independent claim 2. The claim could be amended to recite: “The method according to claim 5, wherein the training step further comprises the steps of: ...”. Also note that this claim recites training at least two learning capable systems while claim 2 recites training at least one learning capable system, which would also suggest that claim 6 is an independent claim.

#### **Claim 11**

The claim recites: “A method for using a learning-capable system trained according to the method of claim 2 by applying input data of a subject to generate an outcome of the learning-capable system, further comprising correcting the outcome with respect to a predetermined reference subject. This claim should also be amended to make it clear that this is a dependent claim further limiting claim 2. The claim could be amended to recite: “The method according to claim 2 wherein input data of a subject is applied to the trained learning-capable system to generate an outcome of the learning-capable system, and the method further comprises correcting the outcome with respect to a predetermined reference subject”.

**Claim 12**

“The method for using at least two learning-capable systems trained according to the method of claim 7...” However, claim 7 is not a method for using the learning capable system. The claim could be amended to recite: “The method according claim 7, wherein input data of a subject is applied to at least two learning-capable systems to generate output data from the learning-capable systems, said applying input data comprising the steps of:...”

**Claim 13**

A method of creating a composite training data set, in particular for use in training a learning-capable system according to the method of claim 2, comprising the steps of:...” This claim should also be amended to make it clear that this is a dependent claim further limiting claim 2. The claim could be amended to recite: “The method according claim 2 further comprising creating a composite training data set, said creating comprising the steps of:...”

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. In light of the amendments made on the claims, the rejection under 35 USC 112 made on the previous Office Action is withdrawn.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There are two separate requirements set forth in this paragraph:

- (A) the claims must set forth the subject matter that applicants regard as their invention; and
- (B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

The first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. The second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite — i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art.

Claims are not just words listing out invention elements...they are limitations that define the fundamental claim scope. Although an essential purpose of the examination

Art Unit: 2129

process is to determine whether or not the claims define an invention that is both novel and nonobvious over the prior art, another essential purpose of patent examination is to determine whether or not the claims are **precise, clear, correct, and unambiguous**. The uncertainties of claim scope should be removed, as much as possible, during the examination process.

### **Claims 2, 17 and 18**

The claim recites “augmenting the input data set **and/or** the outcome data set”. The claim does not specify under what conditions or how it is determined when the input data set is augmented or when the output data set is augmented or when both should be augmented. The claim also recites “training each learning-capable system using the augmented input data set **and/or** the augmented outcome data set”. However, there is no description of how it is determined whether to use the augmented input data, the augmented output data or both to train the system. Lacking this description in the claim, the intent of these limitations in the claimed invention cannot be established and the metes and bounds of the claim are not clear to a person of ordinary skill in the arts.

The claim also recites: “augmenting the input data of each subject by its propensity score data and/or its stratum assignment” in lines 15-16. However, lines 6-7 recite: “augmenting the input data set **and/or** the outcome data set according to predetermined criteria”. As such, the claim does not require that the input data set be augmented since the claim provides for optionally augmenting the input data, the outcome data or both and there is nothing in the claim as to how it is determined which of the data is

Art Unit: 2129

augmented. The intent of this limitation is not clear and the metes and bounds of the claimed invention cannot be determined.

Claims 17 and 18 recite limitations similar to those of claim 2 and are rejected on the same basis.

### ***Claim Rejections - 35 USC § 101***

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-16 and 19-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The portions of the opinions in State Street and AT&T relying **solely** on a “useful, concrete and tangible” result analysis should no longer be relied on. Ex parte Bilski, Appeal No. 2007-1130 (Fed. Cir. October 30, 2008).

The court has said that there's a two-pronged test to determine whether a **software of business method process** patent is valid: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. In other words, pure software or business method patents that are neither tied to a specific machine nor change something into a different state are not patentable. Ex parte Bilski, Appeal No. 2007-1130 (Fed. Cir. October 30, 2008).

Furthermore, the preamble is not given any patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained



Art Unit: 2129

description of the structure not depending for completeness upon the introductory clause. Kropa v. Robie, 88 USPQ 478 (CCPA 1951). An intended use clause found in the preamble is not afforded the effect of a distinguishing limitation unless the body of the claim sets forth structure which refers back to, is defined by, or otherwise draws life and breath from the preamble. In re Casey, 152 USPQ 235 (CCPA 1967).

Claims 1-16 and 19-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. For a method (or process) claim to be statutory under 35 USC 101, the method must be tied to another statutory class (such as a particular apparatus) or transform underlying subject matter (such as an article or materials) to a different state or thing. Therefore, the claim must positively recite the apparatus that accomplishes the method steps or positively recite the subject matter that is being transformed.

### **Response to Applicant's arguments**

11. The Applicant's arguments regarding the rejection of claims 1-16 and 19-20 have been fully considered but are not persuasive.

#### **In reference to Applicant's arguments:**

The examiner rejected claims 1-20 under 35 USC 101 as being directed to nonstatutory subject matter. The claims are amended such that they are statutory under *Ex parte Bilski*, by tying the claimed method to a particular machine or apparatus. The rejection, therefore, should be withdrawn.

Art Unit: 2129

**Examiner's response:**

The claims as amended do not suggest that there is a particular machine implementing the method. None of the limitations of claim 2 seem to reasonably require or suggest a computer or any type of machine for implementing the method. The claim merely recites a "learning capable system". However, this learning-capable system could be a human that can learn to perform the steps in the claimed method. As such, the method claims have not been tied to another statutory category for implementing the method and are not statutory under 35 USC 101.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 2-9 and 11-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnhill et al. (US Patent #6,306,087, referred to as **Barnhill**).

**Claims 2, 17 and 18**

Barnhill anticipates training at least one learning-capable system (**Barnhill**: abstract; C6, L14-20; C18, L22-33; C23, L48 to C25, L47; Examiner's Note (EN): learning capable system not further defined to any specific type of system. Neural Networks are learning capable systems since they must be trained to perform a particular function) comprising the steps of:

Art Unit: 2129

providing a predetermined training data set corresponding to input data for each of a respective predetermined number of subjects comprising a predetermined input data set and a predetermined outcome data set (**Barnhill**: C6, L14-44; C7, L39-61; C12, L59 to C13, L18; C18, L22-67; C21, L15 to C22, L6; EN: item 19 applies. The training data is a set of input values paired with known classification results. Moreover, it is inherent in back propagation learning to have a data set of values and the expected outcome of those values in order to determine the error between the expected output and the output produced by the network so that weights can be modified accordingly),

augmenting the input data set and/or the outcome data set according to predetermined criteria (**Barnhill**: C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C15, L1-38; C23, L48 to C25, L47; C30, claim 1; EN: item 19 applies. Augmenting not further defined to any particular process. The preprocessing of the training data is considered “augmenting” the data. Moreover, as a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation), and

training each learning-capable system using the augmented input data set and/or the augmented outcome data set, through the use of a computing device (**Barnhill**: C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C15, L1-38; C23, L48 to C25, L47; C30, claim 1), wherein the augmenting step comprises the steps:

Art Unit: 2129

estimating propensity score data for each said subject depending on corresponding input data (**Barnhill**: C6, L14-44; C7, L39-61; C12, L59 to C13, L18; C15, L1-38; C18, L22-67; C21, L15 to C22, L6; C23, L48 to C25, L47; Fig. 5; EN: item 19 applies. Propensity score data not further defined. Identifying the group to which each sample in the training data set belongs to is considered a propensity score. Also note the test for discriminating power and the scaling of the training data),

dividing the propensity score data into at least two strata (**Barnhill**: C6, L32-44; C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C15, L1-38; C23, L48 to C25, L47; EN: the groups to which the data belongs to (the diagnosis) is strata),

assigning each subject to a stratum according to predetermined criteria (**Barnhill**: C6, L32-44; C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C15, L1-38; C23, L48 to C25, L47; EN: each sample will belong to a group), and

augmenting the input data of each subject by its propensity score data and/or its stratum assignment (**Barnhill**: C6, L32-44; C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C15, L1-38; C23, L48 to C25, L47; C30, claim 1; Fig. 5; EN: item 19 applies. Augmenting not further defined to perform any specific modification on the data. Any modification of the training data could be considered "augmenting").

### Claim 3

Barnhill anticipates the training step comprises the step of optimizing the operating point parameters within each stratum (**Barnhill**: C15, L1-38; C18, L22-67; C21, L15 to C22, L6; Fig. 5; EN: item 19 applies. Adjusting the network weights to

Art Unit: 2129

reduce the error between the network outputs and the target values is considered optimizing the operating point parameters for the stratum).

#### **Claim 4**

Barnhill anticipates the operating point parameters are optimized such that the median of all output data of users assigned to each stratum vanishes (**Barnhill**: C15, L1-38; C21, L15 to C22, L6; EN: scaling the training data. Also note the diagnostic index computed for each output neuron).

#### **Claim 5**

Barnhill anticipates the augmenting step comprises the step of: generating a plurality of augmented training data sets by augmenting the input data set using a predetermined statistical model (**Barnhill**: C6, L32-44; C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C15, L1-38; C23, L48 to C25, L47; Fig. 5; EN: statistical model not further defined).

#### **Claim 6**

Barnhill anticipates training at least two learning-capable systems, wherein the training step comprises the steps of: training each learning-capable system using a subset of the plurality of augmented training data sets (**Barnhill**: C6, L32-44; C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C23, L48 to C25, L47), constructing scores for each outcome for each trained learning-capable system (**Barnhill**: C6, L32-44; C7, L39-

Art Unit: 2129

61; C12, L59 to C13, L18; C13, L28-60; C23, L48 to C25, L47; C30-32, claims 1-4), and determining characteristics of the distributions of the scores for each subject (**Barnhill**: C6, L32-44; C7, L39-61; C12, L59 to C13, L18; C13, L28-60; C23, L48 to C25, L47; C30-32, claims 1-4).

### Claim 7

Barnhill anticipates the input data set is augmented using a generalized Markov chain Monte-Carlo method (**Barnhill**: C23, L48 to C25, L47; C32, claim 5).

### Claim 8

Barnhill anticipates the augmenting step comprises the steps of: providing a further learning capable-system and a further predetermined training data set comprising a further predetermined input data set and a further predetermined outcome data set for each of a respective further predetermined number of subjects (**Barnhill**: C6, L32-44; C6, L66 to C7, L16; C13, L28-60; C18, L22-67; C23, L48 to C25, L47; C30-32, claims 1-4), training the further learning-capable system using the further predetermined training data set (**Barnhill**: C6, L32-44; C6, L66 to C7, L16; C13, L28-60; C18, L22-67; C23, L48 to C25, L47; C30-32, claims 1-4), and augmenting the input data set by **at least one** additional input variable taken from the further predetermined input data set, further predetermined outcome data set **and/or** internal output data obtained from the trained further learning-capable system (**Barnhill**: C6, L32-44; C6, L66 to C7, L16; C13, L28-60; C18, L22-67; C23, L48 to C25, L47; C30-32, claims 1-4).

Art Unit: 2129

**Claim 9**

Barnhill anticipates the additional input variables comprise all further input data and all further outcome data of a subset of subjects of the further training data set (**Barnhill**: C6, L32-44; C6, L66 to C7, L16; C13, L28-60; C18, L22-67; C23, L48 to C25, L47; C30-32, claims 1-4).

**Claim 11**

Barnhill anticipates a method for using a learning-capable system trained according to the method of claim 2 by applying input data of a subject to generate an outcome of the learning-capable system, further comprising correcting the outcome with respect to a predetermined reference subject (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L18; C18, L22—67; C21, L15 to C22, L6; EN: comparing the output to a target output and adjusting the network to correct the error).

**Claim 12**

Barnhill anticipates method for using at least two learning-capable systems trained according to the method of claim 7 by applying input data of a subject to generate output data of the learning-capable systems, comprising the steps of: presenting the input data of the subject to each of the learning-capable systems and constructing a score for the output data obtained from the learning-capable systems (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22—67; C21, L15 to C22, L6; C23, L48 to C25, L47; C30-32, claims 1-4).

Art Unit: 2129

**Claim 13**

Barnhill anticipates a method of creating a composite training data set, in particular for use in training a learning-capable system according to the method of claim 2, comprising the steps of: providing an aggregated evidence data set (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22-67; C21, L15 to C22, L6; C23, L48 to C25, L47; C30, claim 1; EN: item 19 applies. Aggregated evidence data set not further defined. The training data containing values of biomarkers or data from patients corresponding to a disease is considered aggregated data), disaggregating the aggregated evidence data set to obtain a disaggregated training data set based on virtual subjects (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22-67; C19, L27 to C20, L60; C21, L15 to C22, L6; C23, L48 to C25, L47; C30, claim 1; EN: item 19 applies. Disaggregating not further defined to any specific transformation of data. Scaling the training data is considered disaggregating the evidence data. Also note the Input Data Preprocessing where the raw input data is processed to remove noisy data), and merging the disaggregated training data set with a further training data set to produce the predetermined training data set (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22-67; C19, L27 to C20, L60; C21, L15 to C22, L6; C23, L48 to C25, L47; C30-31, claims 1 and 2).

**Claim 14**

Barnhill anticipates the merging step comprises the step of choosing a real training data set based on real subjects as the further training data set (**Barnhill**: C6,



Art Unit: 2129

L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22-67; C19, L27 to C20,L60; C21, L15 to C22, L6; C23, L48 to C25, L47; C30, claim 1; EN: The different data obtained from different subjects are considered real training data sets).

### **Claim 15**

Barnhill anticipates the disaggregation step comprises the step of assigning **at least a value of one** auxiliary variable to each virtual subject of the disaggregated training data set according to predetermined criteria (**Barnhill**: C13, L28-60; C15, L1-38; C19, L27 to C20, L65; C23, L48 to C25, L47; C30-31, claims 1 and 2; EN: item 19 applies. Auxiliary variable not further defined to any specific type).

### **Claim 16**

Barnhill anticipates the predetermined training data set is provided by: providing an aggregated evidence data set (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22-67; C21, L15 to C22, L6; C23, L48 to C25, L47; C30, claim 1; EN: item 19 applies. Aggregated evidence data set not further defined. The training data containing values of biomarkers or data from patients corresponding to a disease is considered aggregated data), disaggregating the aggregated evidence data set to obtain a disaggregated training data set based on virtual subjects (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22-67; C19, L27 to C20,L60; C21, L15 to C22, L6; C23, L48 to C25, L47; C30, claim 1; EN: item 19 applies. Disaggregating not further defined to any specific transformation of data. Scaling the training data is considered

Art Unit: 2129

disaggregating the evidence data. Also note the Input Data Preprocessing where the raw input data is processed to remove noisy data), and merging the disaggregated training data set with a further training data set to produce the predetermined training data set (**Barnhill**: C6, L32-44; C7, L39-61; C12, L38 to C13, L60; C18, L22-67; C19, L27 to C20, L60; C21, L15 to C22, L6; C23, L48 to C25, L47; C30-31, claims 1 and 2).

### **Claim 19**

Barnhill anticipates the input data set is augmented using a generalized Markov chain Monte-Carlo method (**Barnhill**: C23, L48 to C25, L47; C32, claim 5).

### **Claim 20**

Barnhill anticipates the disaggregation step comprises the step of assigning at least a value of one auxiliary variable to each virtual subject of the disaggregated training data set (**Barnhill**: C13, L28-60; C15, L1-38; C19, L27 to C20, L65; C23, L48 to C25, L47; C30-31, claims 1 and 2).

### **Response to Applicant's arguments**

14. The Applicant's arguments regarding the rejection of claims 2-9 and 11-20 have been fully considered but are not persuasive.

#### **In reference to Applicant's arguments:**

In contrast, Barnhill et al. disclose a computer-assisted method for diagnosing

Art Unit: 2129

disease that does not make use of propensity scores. The examiner considers identifying the group to which each sample in the training data set belongs to be a propensity score. The applicants respectfully disagree. A propensity score relates to a conditional probability, such as the probability of a data unit being assigned to a particular condition in a study given a set of known covariates. Thus, an identification of the actual group to which a sample belongs is not a propensity score. Such an identification would not look forward or provide any meaningful training information, but rather would always give a score of 100% based on a snapshot of a current grouping, giving no weight to possible groupings that would necessarily have value during a training process. Barnhill et al. do not disclose or suggest estimation of propensity score data.

**Examiner's response:**

As stated in the argument above, a propensity score is a probability of a data unit being assigned to a particular condition. As disclosed by Barnhill, patient data is received from a patient and a diagnostic value is determined in order to determine if the patient has a particular disease. Patient data is collected, the data that is associated to a disease is selected, tests are performed for analyzing the discriminating power of this data, individual values are grouped and this data is used to train a neural network that determines a diagnostic value for the patient that indicates if the user may have or is susceptible to a disease (**Barnhill**: C1, L37-63; C7, L39-61; C15, L1-38; C23, L48 to C25, L47). The diagnostic index is considered a propensity score since it is used to identify if a patient has a particular condition based on the data received. Selecting the

Art Unit: 2129

data associated to a disease and determining the discriminating power of this data is also a propensity score that is used to determine which data is descriptive of a particular disease. Moreover, the claim has not described any specific way in which this propensity score is estimated, only that it depends on input data received from a patient and as such any value computed used to how to determine if the data received from a patient reflects that the patient has or could develop a disease is considered to determine a propensity score.

**In reference to Applicant's arguments:**

The examiner also asserted that any modification of the training data could be considered to be "augmenting" under claim 2. Again, the applicants respectfully disagree. Claim 2 specifically recites that the input data of each subject is augmented by its propensity score data and/or its stratum assignment, and therefore any general modification of the data does not satisfy the requirements of this claim. Thus, Barnhill et al. also do not disclose or suggest the claimed augmenting step.

**Examiner's response:**

As set forth above, augmenting has not been defined in the claim as to what augmenting the input data entails. The claim reads augmenting the input data by its propensity score **and/or** its stratum assignment but provides no description as to how it is determined if the input data is to be augmented by its propensity score, by the stratum data assignment or both. Barnhill discloses selecting the data that is associated to a disease and scaling this data. The discriminating power for this data is

Art Unit: 2129

determined and this data is preprocessed (scaling, truncation, linear/non-linear combination, etc) and these values optionally with one or several secondary values are sent to a trained neural network. Also note that the inputs are grouped together into subsets and inputs from each subset are used to form a list of actual inputs fed into the classifiers based on the discriminating power of the inputs (**Barnhill**: C6, L32-44; C12, L59 to C13, L18; C23, L48 to C25, L47; C30, claim 1). As such, the input data received from the patient is “augmented” based on the discriminating power, which is considered a propensity score.

It is also noted that, based on the definition provided by the Applicant for propensity score, this is a numerical value. It is not clear what it means to augment data received from a subject with a propensity score (a value). This data received from a subject (which has not been defined to any specific type of data) could be data relating to different features of the subjects and different values for these features. As such, based on the definition provided by the Applicant and the language used in the claim, it is not sufficiently clear what it means to augment the input data received from the subjects, which could relate to different features with different values, by a propensity score, which is a single value.

### **Examination Considerations**

15. Examiner has cited particular columns and line numbers (or paragraphs) in the references applied to the claims above for the convenience of the applicant. Although the specified citations are representative of the teachings of the art and are applied to

Art Unit: 2129

specific imitations within the individual claim, other passages and figures may apply as well. It is respectfully requested from the Applicant in preparing responses, to fully consider the references in their entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner. The entire reference is considered to provide disclosure relating to the claimed invention.

16. The claims and only the claims form the metes and bounds of the invention. "Office personnel are to give the claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 105455, 44USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. In re Prater, 415 F.2d, 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969)" (MPEP p 2100-8, c 2, I 45-48; p 2100-9, c 1, I 1-4). The Examiner has full latitude to interpret each claim in the broadest reasonable sense. Examiner will reference prior art using terminology familiar to one of ordinary skill in the art. Such an approach is broad in concept and can be either explicit or implicit in meaning.

17. Examiner's Notes are provided with the cited references to prior art to assist the applicant to better understand the nature of the prior art, application of such prior art and, as appropriate, to further indicate other prior art that maybe applied in other office actions. Such comments are entirely consistent with the intent and spirit of compact prosecution. However, and unless otherwise stated, the Examiner's Notes are not prior

Art Unit: 2129

art but a link to prior art that one of ordinary skill in the art would find inherently appropriate.

18. Unless otherwise annotated, Examiner's statements are to be interpreted in reference to that of one of ordinary skill in the art. Statements made in reference to the condition of the disclosure constitute, on the face of it, the basis and such would be obvious to one of ordinary skill in the art, establishing thereby an inherent prima facie statement.

19. Examiner's Opinion: items 16-18 apply. The claims and only the claims form the metes and bounds of the invention. The Examiner has full latitude to interpret each claim in the broadest reasonable sense.

### ***Conclusion***

20. Claims 2-20 are rejected.

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 2129

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Correspondence Information***

22. Any inquires concerning this communication or earlier communications from the examiner should be directed to Omar F. Fernández Rivas, who may be reached Monday through Friday, between 7:00 a.m. and 4:00 p.m. EST. or via telephone at (571) 272-2589 or email [omar.fernandezrivas@uspto.gov](mailto:omar.fernandezrivas@uspto.gov).

If you need to send an Official facsimile transmission, please send it to (571) 273-8300.

If attempts to reach the examiner are unsuccessful the Examiner's Supervisor, David Vincent, may be reached at (571) 272-3080.

Hand-delivered responses should be delivered to the Receptionist @ (Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22313), located on the first floor of the south side of the Randolph Building.

/Omar F. Fernández Rivas/  
Examiner, Art Unit 2129  
Tuesday, September 08, 2009.

/David R Vincent/  
Supervisory Patent Examiner, Art Unit 2129